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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,502	02/05/2004	David B. Rozema	Mirus.042.03	5669

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MIRUS CORPORATION
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EXAMINER

MAKAR, KIMBERLY A

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/772,502</p>	<p>Applicant(s)</p> <p align="center">ROZEMA ET AL.</p>	
	<p>Examiner</p> <p align="center">Kimberly A. Makar, Ph.D.</p>	<p>Art Unit</p> <p align="center">1636</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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DETAILED ACTION

Response to Arguments

1. Currently, claims 13-30 are pending. In the office action dated 12/18/06, Claims 13, 16-17, and 22-24 are rejected under nonstatutory obvious-type double patenting over US Patent 7,098,032. Claims 13-22 and 25-30 are rejected under 35 USC 102(e) as being anticipated by Meier et al (US patent No: 6,616,946). Claims 23-24 are rejected under 35 USC 103(a) as being unpatentable over Meier (US patent No: 6,616,946) in view of Merdan et al (Prospects for cationic polymers in gene and oligonucleotide therapy against cancer, Advanced Drug Delivery Reviews, 2002. 54:715-758). Any rejection not maintained in this office action is withdrawn thereby rendering applicant's arguments moot.
2. In the response to the office action dated 12/18/06, applicant has amended claim 13 to recite, "A composition for delivery of polynucleotides to a cell comprising: the polynucleotide and a[n] amphiphilic membrane active polyvinylether." Applicant argues that this amendment obviates the double-patenting, 102(e) and 103(a) rejections from the prior office action. This argument is not persuasive.
3. Applicants define "membrane active" as, "polymers or compounds are molecules that are able to alter membrane structure" (page 9, lines 12-13). Applicant teaches that, "sufficient hydrophobicity incorporated into the polyvinylether can give the polymer membrane activity" (page 7, lines 30-31).
4. US Patent 7098032 teaches amphiphilic polymers (column 20, lines 64- column 21) and "Membrane Active" compounds (column 21, 12-31). Additionally, claims 11-13,

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18-21 deal with the making an amphipathic copolymer comprising a polycation and a polyanions. Example 2 of Patent 7,098,032 uses a polyvinyl ether to produce polycations, which are used in the amphiphilic copolymers of the claim 11. Thus the use of the term "amphiphilic membrane active" does not obviate the obvious-type double patenting rejection of instant claims 13, 16-17 and 22-24 over Patented claims 11-13, and 18-21. The double patenting rejection is maintained for reasons stated in the office action dated 12/18/06.

5. Meier et al (US Patent 6,616,946) teaches amphipathic copolymer particles that comprise polyvinylethers (column, 8, lines 31-35). Meier also teaches that these copolymer particles are expressly made for nucleotides and drug delivery as an advance over liposomes (column 1, lines 10-60). He also states that these particles are modified to comprises targeting molecules, such as antibodies, and that "antibodies may be directed to specific cell surface molecules or antigens expressed when a cell type becomes diseases, for example a cancer" (column 15, lines 50-64). An inherent property of these amphipathic particles would be the ability to alter membrane structure, through the attachment of the antibodies to the cell membrane, but also as delivery vehicles which fuse to the cells for delivery purposes, as replacements for liposomes. Thus the phrase "amphiphilic membrane active polyvinylether" is not persuasive to overcome the 102(e) or 103(a) rejections of the office action dated 12/18/06. Thus the 102(e) rejection over claims 13-22 and 25-30 and 103(a) rejection over claims 23-24 from the previous office action are maintained for the reasons stated therein.

Conclusion

6. No claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/05/02/07


DAVID GUZO
PRIMARY EXAMINER